

III.**510(k) SUMMARY**

(As required by 21 C.F.R. 807.92)

A. Submitter Information

Submitter's Name: Thomas Medical Products, Inc.
Address: 65 Great Valley Parkway
Malvern, PA 19355
Telephone Number: (610) 296-3000
Facsimile: (610) 296-4591
Contact Person: Tim Stoudt
Title: Manager, Quality Engineering
Date Submission Prepared: May 25, 2001

B. Device Information

Trade name: Not assigned at this time.
Classification Names: Trocar (21 C.F.R. §870.1390)

Predicate Devices: Cook, Transseptal Needle, Daig, Transseptal Needle and C.R. Bard, USCI® Brockenbrough® Needles and Accessories

Device Description: The Thomas Medical Transseptal Needle consists of a specifically curved distal portion to accommodate positioning in the cardiac anatomy when used in conjunction with a transseptal introducer. A stopcock is attached to the proximal end of the needle for air aspiration, fluid infusion, blood sampling and pressure monitoring. A pointer is included on the needle shield to show orientation of the curve.

Intended Use: The Transseptal Needle is designed to create the primary puncture in the interatrial septum when passing an introducer and/or catheter through the septum from the right side of the heart to the left side.

C. Comparison of Required Technological Characteristics

The technological characteristics of the Modified Device are the same as the Predicate Device.

D. Substantial Equivalence

The Thomas Medical Products Transseptal Needle has the same general intended use/indications for use and technological characteristics as other legally marketed devices. Therefore, based on the similarities in intended use and technological characteristics, the Thomas Medical Products Transseptal Needle is substantially equivalent to the legally marketed predicate devices.

D. Qualification Testing

Thomas Medical Products qualification testing of the Transseptal Needle included dimensional, visual, leak testing, Needle to Hub pull test, Hub to Stopcock pull test, Wire to Handle pull test and Needle to Hub torque force. All samples passed the protocol qualification testing requirements.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tim Stoudt
Manager, Quality Engineering
Thomas Medical Products, Inc.
65 Great Valley Parkway
Malvern, PA 19355

MAY 02 2002

Re: K011727
Transseptal Needle/Trocar
Regulation Number: 870.1390
Regulation Name: Trocar
Regulatory Class: II (two)
Product Code: 74 DRC
Dated: March 11, 2002
Received: March 12, 2002

Dear Mr. Stoudt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donna-Bea Tillman", is written over the typed name.

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011727

Device Name: Transseptal Needle

Indications For Use:

Used to create the primary puncture in the interatrial septum when passing an introducer and/or catheter through the septum from the right side of the heart to the left side.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ☐

(Optional Format 1-2-96)


Division of Cardiovascular & Respiratory Devices
510(k) Number K011727